IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.	:	10/761,387	Confirmation No. 2425
Applicant(s)	:	Vigil et al.	Customer No. 23838
Filed:	:	22 Jan. 2004	
Art Unit	:	3763	
Title:	:	METHOD FOR DELIVERING MEDICATION INTO AN ARTERIAL WALL FOR PREVENTION OF RESTENOSIS	
Examiner	:	Bouchelle, Laura	

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Pre-Appeal Brief Request For Review

S I R:

In response to the Final Office Action of May 22, 2009, Applicants request pre-appeal review of this application for the reasons stated in the attached sheets. This Request is being filed concurrently with a Notice of Appeal.

Arguments are provided in the attached 4 sheets (pages 2-5).

Arguments In Support Of Pre-Appeal Brief Request For Review

The pending Final Office Action rejects independent claims 1 and 10 under § 103(a) as being unpatentable over Vigil '716 (US 5,746,716) in view of Edwards (US 6,009,877). Applicants respectfully submit that this rejection is clearly erroneous because the Examiner uses an overly simplistic and incomplete statement of motivation for the proposed modification, and has not provided the proper evidentiary basis for the correct statement of motivation. Accordingly, the Examiner has not made a *prima facie* case of obviousness.

The invention of independent claims 1 and 10 is a method for releasing medicaments into a blood vessel wall. The method uses an expanding member (e.g., a balloon) having a plurality of dispensers (e.g., injection needles). The expanding member is configured such that the dispensers "consist[] only of dispensers positioned in a single plane." An example of this feature is demonstrated in the embodiment shown in FIG. 2 of the present application, where the dispensers 20 are all positioned in only a single plane 19.

The Examiner concedes that the balloon device disclosed by Vigil '716 (see, e.g., FIG. 2) does not have this feature. However, the Examiner suggests that the balloon device of Vigil '716 can be modified to use only a single plane of injectors, relying on the "basic teaching" that "when a tissue is being treated[,] it is desirable that the damage done to the tissue by the treatment is minimized." (Office Action dated 5/22/09 at pg. 2, para. 3). Edwards is cited as providing evidentiary support for this general teaching in the art.

The Examiner's reasoning is clearly erroneous for at least two reasons. First, using this "basic teaching" of minimizing tissue damage during treatment as the *sole* statement of motivation in the rejection is improper because it is overly simplistic and incomplete in view of the complexity of the decision-making that goes into the designing of medical devices for the treatment of blood vessels, such as the critically important coronary arteries. In view of the real world complexity of the problem, this statement of motivation is too "basic." Second, Edwards does not provide the proper evidentiary support for the correct statement of motivation.

The Examiner's statement of motivation is incorrect.

In the context of treating blood vessels using the balloon injector device of Vigil '716, relying on the basic teaching that tissue damage should be minimized during treatment as the

sole source of motivation is improper because it is overly simplistic and incomplete. Someone of ordinary skill in the art seeking to redesign the balloon injector device of Vigil '716 would be required to consider numerous design factors, including, for example, its ease of use, clinical effectiveness, cost of manufacture, durability, safety, cost of materials, etc. The risk of tissue damage when using the device is but one of these many design considerations; and all these design considerations, many of which are competing, must be properly balanced. For example, reducing the cost of manufacture is certainly a motivation in the art, but that is not the sole motivation. Lower cost of manufacture must be balanced against quality and safety considerations.

Likewise, it is a general principle in medical treatment that both the risks and benefits of the treatment must be considered and properly balanced. When using the balloon injector device of Vigil '716, reducing the risk of tissue damage during the injection procedure is one consideration, but there is a countervailing consideration of providing effective treatment, which may require inflicting at least some tissue damage. Simply reducing all risk of injury, as the lone goal, is not an acceptable nor an effective way of delivering medical treatment. Proper delivery of medical treatment requires the balancing of both risks and benefits.

Thus, in considering only the medical procedure's risk of tissue damage without considering its benefits (i.e., its therapeutic effectiveness), the Examiner's statement of motivation is incomplete. In this context, a better statement of motivation would be as follows: *it is desirable to minimize tissue damage while still providing effective treatment.* However, even this statement of motivation is incomplete because it states the goal, but not how to achieve that goal. Thus, a proper and complete statement of motivation to modify the device of Vigil '716 in the manner proposed by the Examiner would be as follows: *it is desirable to treat blood vessels using a single plane of dispensers, instead of multiple planes of dispensers, because it would minimize tissue damage while still providing effective treatment.* In view of the real world complexity involved in the treatment of blood vessels, simply stating that it is desirable to minimize tissue damage is not an adequate statement of motivation.

Edwards does not provide the proper evidentiary support for the motivation.

The above-noted complete and proper statement of motivation could be supported by prior art demonstrating that treatment of vascular disease by using focal injection of drug at a

single segment of the blood vessel can be just as effective as multiple injections across multiple segments of the blood vessel. Edwards, however, provides no such evidentiary support for this statement of motivation.

Edwards has nothing to do with the treatment of blood vessels or the injection of drugs. As explained in Applicants' prior response dated February 24, 2009, the Edwards device is designed to treat gastroesophageal reflux disease (GERD) in the esophagus using RF energy delivered via electrodes. As background, Edwards explains that GERD is due to a dysfunction of the lower esophageal sphincter (LES).[1] Edwards further discloses that one of the possible causes of GERD may be aberrant electrical signals in the LES.[2] As such, Edwards provides a device for treating a gastrointestinal sphincter, such as the lower esophageal sphincter. The device operates by delivering energy, such as RF energy, to the target site.[3] For example, FIG. 14 of Edwards (as pointed out by the Office Action) shows a basket assembly having needle electrodes 90 for delivering RF energy to the target tissue.[4]

In contrast to the blood vessel treatment device of Vigil '716, the device of Edwards is for treating a different part of the body, for a different disease condition, using a different treatment modality. Because Edwards discloses nothing about treating blood vessels by injecting drugs into the blood vessel walls, Edwards provides no evidentiary support for the statement of motivation that it is desirable to treat blood vessels using a single plane of dispensers, instead of multiple planes of dispensers, because it would minimize tissue damage while still providing effective treatment.

Summary

The Examiner's reasoning is clearly erroneous for at least two reasons. First, using the "basic teaching" of minimizing tissue damage during treatment as the sole statement of motivation in the rejection is improper because it is overly simplistic and incomplete in view of the complex decision-making that goes into the designing of medical devices for the treatment of blood vessels. Second, Edwards does not provide the proper evidentiary support for the correct statement of motivation.

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1 See, e.g., col. 1, lns. 29-32.
2 See, e.g., col. 1, lns. 53-55.
3 See, e.g., col. 8, lns. 22-46.
4 See col. 9, lns. 48-60.

CONCLUSION

Applicants respectfully submit that the Examiner's final rejection is clearly erroneous. Accordingly, favorable action on this Pre-Appeal Brief Request for Review is respectfully requested.

The Commissioner is authorized to charge all required fees, fees under § 1.17, or all required extension of time fees, or to credit any overpayment to Deposit Account No. 11-0600 (Kenyon & Kenyon LLP).

Respectfully submitted,

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